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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,478	11/20/2000	Emory V. Anderson	24727-813C	9900

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/26/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,478

Applicant(s)

ANDERSON ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 08-22-02 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed August 22, 2002 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "substantially optimally" in claim 12 is a relative term which renders the claim indefinite. The term "substantially optimally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term substantially optimally does not clearly indicate to what degree the wavelength reflects from the region of the test strip.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-4 and 8-9, 16-18, 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly (WO96/13707) in view of Manfred Augstein (USP#5,665,310).

Connolly illustrates how to read the surface of a test strip with an optical reading apparatus. This apparatus contain a separate optical readhead that determines color and shade of a test strip while being inserted (pg. 3, lines 33-35). One or more light sources for high intensity light emitting diodes (LED) are located in housing to illuminate the test strip while a light detector or sensor is able to take a reading of light reflected from the surface of the test strip that can be adapted to generate or respond to particular wavelengths of light (pg. 17, lines 1-10). Connolly discloses the use of two wavelengths can allow one to define the pseudo endpoint algorithm, which can allow for an increased range of a chemistry reaction (pg. 21, para 3). In addition, Connolly discusses the use of multiple wavelengths to correct problems in positioning the strip in the apparatus (pg. 21, para 4). Connolly teaches an EEPROM unit that is connected to a microprocessor/microcontroller containing measurement parameters, software, calibration data and a means for recognizing a reagent on a test strip (pg. 17, 1st and 2nd para). The photometer includes a separate optical reader head (pg. 3, line 33) light emitting diodes (LED) are contained in a housing to illuminate the test strip containing the sample (pg. 17, lines 1-5). An immunoassay can be performed on the test strip

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using immunological reagents that generate specific signals when exposed to a target analyte (pg. 3, lines 21-23). When the proper amount of a sample is applied to the strip, the apparatus goes through three measurement cycles, with the third measurement determining the final density. The density is compared to a table of values through the use of an algorithm stored in the EEPROM (pg. 19, 2nd para). Chromophore indicators are used along with multiple wavelengths to better enhance the range of chemistry on a test strip (pg. 21, 2nd para). Also the use of fluorescent labels is used for analyte detection (pg. 14, table VIII). Once the analyte is determined on a test strip, it produces color (pg. 19, lines 12-16).

Although the apparatus of James Connolly comprises a reader head, he does not specifically point out the ability of the reader head to move.

However, Manfred Augstein teaches an apparatus for analyzing a sample on a test strip that comprises a measuring head. The measuring head moves along the test strip to measure the remission values of the test (col. 2, lines 26-40). The measuring head is moved over the test strip with the aid of a drive motor (col. 5, lines 15-23). The advantage of this move head is that test fields (test strips) can be evaluated with only one measuring head as it moves across (uniformly) to evaluate the sample (col. 4, lines 63-66). In addition, various test fields of a test element are examined by moving the measuring head along the direction of the test element (e.g. in a stepwise fashion) measuring each test section of the strip (col. 4, lines 26-32).

It would have been obvious to one of ordinary skill in the art to employ the movable measuring head of Manfred Augstein into the photometer of James Connolly to

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provide a head that is mobile in that it is able to read all sections of the test strip that contains the sample to be read.

6. Claims 5-7, 11-12, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein (USP#5,665,310) and in further view of Ralph S. Hernicz (USP#4,659,229).

See above teachings for James Connolly and Manfred Augstein.

Connolly and Augstein differ from the instant invention in failing to specifically disclose an aperture in a readhead and the use of fiberoptic bundles.

Hernicz teaches a readhead that contains an aperture (34) to allow light to transmit through (col. 4, lines 1-2). Hernicz also teaches the use of fiberoptic bundles (54 and 56) for illuminating a sample and measuring reflected light (Summary invention and Figure 3). Such a structure of optical head would provide a new and improved readhead for a spectrophotometer capable of more efficient measurements of multiple samples accurately, with reduced height sensitivity (Summary of the invention section).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have provided in the readhead of Connolly an aperture and fiberoptic bundles as taught by Hernicz, in order to provide a new and improved read for a spectrophotometer capable of more efficient measurements of multiple samples accurately, with reduced height sensitivity. It would have been further obvious to employ the movable measuring head of Manfred Augstein into the photometer of James Connolly to provide a head that is mobile in that it is able to read all sections of the test

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strip that contains the sample to be read. With respect to the wavelengths relative to regions of the test strips, as recited in claims 11 and 12, one of ordinary skill in the art would have found it obvious to illuminate at a particular wavelength over a certain region of the test strip in order to optimize the measurement of the analyte on the test strip, depending on the structure of the test strip.

7. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein and further in view of Senyei et al (WO92/10585) and Wolfgang May (USP#4,963,324).

The teachings of James Connolly and Manfred Augstein are set forth above.

Although James Connolly acknowledges that a variety of analytes can be determined by using detection methods in his apparatus, Connolly and Augstein fail to specifically teach the detection of fetal fibronectin wherein the image forms a stripe when positive for the analyte; (pg. 10, 1st para).

However, Senyei et al teaches a method and assay for detecting fetal fibronectin in a sample (pg. 7, line 3) that indicates normal or ectopic pregnancy (pg. 5, lines 15-28 and pg. 7, lines 15-19). He also teaches that a pink or red spot in the test zone as well as in the control zone of the strip indicates a positive detection of fetal fibronectin. Negative test results of fetal fibronectin, is indicated by a red color in the procedural control area of the test strip (pg. 59, lines 10-14).

Wolfgang May, teaches a colormetric dosimeter having a strip indicator that displays a linear coloration. The indicator is subdivided into regions having different indicating sensitivities (col. 1, lines 1-4). With the high sensitivity region having a strip indicator and a low sensitivity region having a granular indicator are provided. The use of a strip indicator can provide detection in smaller quantities of the analyte; wherein the granular indicator only detects greater quantities of the analyte.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method and assay for detecting fetal fibronectin as taught by Senyei et al in the method of James Connolly of taking multiple wavelengths for a more accurate measurement of fetal fibronectin while using the mobile measuring head of Manfred Augstein that is able to cover all sections of the test strip so that patients with normal or ectopic pregnancy can be determined using color as an indication of test results. Further, one would be motivated to use the color dosimeter comprising a stripe indicator of Wolfgang May, to detect fetal fibronectin in smaller quantities so that patients with critical pregnancy related conditions could test positive at low levels of the analyte.

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein and further in view of Ralph Hernicz as applied to claim 5, and in further view of Senyei et al for the same reasons discussed in the rejection of claim 13 above.

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9. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein for reasons set forth above.

See teachings of James Connolly for the teachings of multiple wavelengths and parameter reading of an analyte. See also the teachings of Manfred Augstein for the mobile measuring head.

With respect to transmitting light onto the surface at an angle normal to the surface and measuring light reflected normally from the surface, the specification does not give a special definition; therefore, the prior art will satisfy the instant claims. In addition, the combined references of Manfred Augstein and James Connolly provide for angle adjustments in the test strip and the mobility of the measuring head to obtain the optimized light transmission of a surface reading as desired. Especially since it held to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." *Application of Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum adjustments of a process by routine experimentation." *Id.* At 458, 105 USPQ at 236-237. The "discover of an optimum adjustment result in a known process is ordinarily within the skill of the art." *Application of Voesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Response to Arguments

12. Applicant's arguments with respect to claims 1, 3-4, and 8-9 have been considered but are moot in view of the new ground(s) of rejection under 103(a).

13. Applicant's arguments filed August 22, 2002 have been fully considered but they are not found persuasive.

14. Applicant's argument to traverse the term "substantially optimally" in claim 12 is not found persuasive. There is no support in the sections of the specification that the applicant draws the examiner's attention to. Therefore, rejection of claim 12 is maintained.

14. Applicant's argument that Hernicz neither teach nor suggest the use of a fiber optic bundle optically coupled to a light emitting diode is not found persuasive. Hernicz teaches an improved measuring head that contain fiberoptic bundles that are contained inside the measuring head. The primary reference of James Connolly teaches the LED (light emitting diodes) are located in the readhead, how the fiberoptic bundles are coupled would be a matter of design choice and the LED will still emit light from the measuring head. Applicant's argument that Hernicz does not teach or suggest light of a first wavelength reflecting equally from all regions of a test strip is not found persuasive

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because the moveable measuring head of Manfred Augstein can be positioned over the region of the test strip to so that the light can be reflected evenly from the first wavelength. The measuring head of Manfred Augstein is mobile and comprise of a guide rail and moves in a stepwise fashion to each position on the test strip (col. 2, lines 30-50). Applicant's argument that Hernicz teaches away from claim 11 by teaching light containing no quantitative or concentration sample information is to be avoided is not found persuasive because Hernicz made adjustments for the light that contained this deficiency by coating on its inner surface with nonreflecting black material so that only the diffuse component of reflectance to pass through the aperture (col. 5, lines 4-10). Therefore, claims 5-7, 11 and 12 are obvious over Connolly in view of Manfred Angstein and further in view of, Hernicz.

Allowable Subject Matter

15. Claim 2 is allowed.

16. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teach or suggest a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture.

17. Claim 2 is dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. Claims 1, and 3-9, and 11-30 are rejected.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



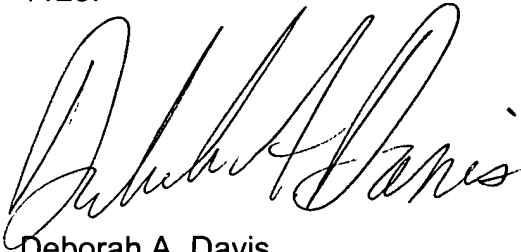
LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/22/02

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

A handwritten signature in cursive script, appearing to read "Deborah A. Davis".

Deborah A. Davis
CM1, 7D16
November 22, 2002